REMARKS

Claims 21-26 are pending in the present application. Applicant notes with appreciation that the Examiner has withdrawn all previous rejections. In an Office Action mailed July 14, 2004, the Examiner has made new rejections. For clarity, the objections and rejections at issue are set forth by number in the order they are addressed herein:

(1) The Examiner objects to the use of the term "Syntex" in Claim 24;

(2) Claims 21-26 are indicated to be rejected under 35 U.S.C. § 112, paragraph one, as allegedly not being enabled.

1. Objection to Claim 24

The Examiner has objected to the use of the term "Syntex" in Claim 24 in reference to an adjuvant, alleging that the trademark term is indefinite in that it identifies the source of goods, not any particular material or product. Applicant respectfully disagrees. The term "Syntex adjuvant formulation" **is**, in fact, the product name for this adjuvant (see, *e.g.*, the specification at page 102, line 8-9), and is well known to those skilled in the art as specifying a particular adjuvant composition. Nonetheless, for business reasons and without acquiescing to the Examiner's arguments, Claim 24 has been amended to replace the term "Syntex adjuvant" with "SAF-1," an alternative term indicating the same compound. Support for the use of this term is found, *e.g.*, in the specification at page102, line 8-9. The amendments to the claim made herein does not alter the scope of the claim, and thus does not narrow the scope of the claim within the meaning of *Festo*[1] or related cases.

2. The rejection under 35 U.S.C. § 112, paragraph one is improper

Claims 21-26 are rejected under 35 U.S.C. § 112, paragraph one, as allegedly failing to comply with the enablement requirement. The Examiner has acknowledged that the specification teaches the construction of the multivalent composition used in the claimed methods (Office Action, page 3). The Examiner has also acknowledged that the working examples of the invention teach how to administer the multivalent compound as a treatment of B-cell lymphoma (Office action mailed June 17, 2003, page 3). The Examiner now asserts that

[1] *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002)

the specification does not teach one of skill in the art how to use the invention to the full scope of the claims because of alleged insufficiency of guidance and objective evidence of efficacy (Office action, page 3). Applicant strongly disagrees and submits that the Examiner's rejection is improper under the law.

The question of pharmaceutical efficacy is clearly outside the scope of the patent statute. The Office must confine its review of patent applications to the statutory requirements of the patent law. M.P.E.P. 2107.03. Further, it is *improper* for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. (M.P.E.P. 2107.03 (V), citing In re Sichert, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); In re Anthony, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); In re Watson, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); In re Krimmel, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); Ex parte Jovanovics, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981). Yet the sole basis for rejection is just such a request for evidence of efficacy. The rejection is based on considerations that are beyond the scope of the statutory requirements of patent law, and is thus improper and should be removed.

Furthermore, the present claims are fully enabled under §112, paragraph one, and the Examiner has provided no evidence to support a contrary conclusion. The Examiner argues that cancer treatments are, in general, unpredictable, and particularly asserts 1) the unreliability of *in vitro* studies of anticancer drugs; and 2) the unpredictability of antibody treatments of tumors. Neither of these arguments is relevant in the present case. In the first instance, the Examiner discusses the screening of unknown chemical compounds *in vitro*, and the difficulties in extrapolating the data to *in vivo* protocols. However, the Applicant is *not* claiming methods of treatment using unknown chemical compounds. In the second instance, the discussion of the difficulties in using antibodies targeted at tumors relates only to passive immunotherapy. Passive immunotherapy is not related to the present invention, in which the tumor-derived idiotypic proteins are used as antigens to elicit an immune response. Thus, neither of these discussions is sufficiently related to the present invention to support the Examiner's assertion that the methods of the present invention are somehow unpredictable and not enabled. Nonetheless, for business reasons and without acquiescing to the Examiner's arguments, Claim 21 has been amended to recite "A method of administering a multivalent composition, . . ." By making this amendment, Applicant does not disclaim any breadth, and in no way suggests that treating B-cell lymphoma is outside the scope of the claims as amended. As this amendment does not narrow

the scope of the claim, the amendment does not narrow the scope of the claim within the meaning of *Festo*[1] or related cases.

To summarize, the Applicant is claiming a method of administering a multivalent composition, the multivalent composition being derived from the patient's lymphoma cells. As acknowledged by the Examiner, the Applicant has enabled the construction of the compositions used in the claimed method, and has enabled the administration of the compositions. Thus, the specification *does* provide written description of the invention, and of the manner and process of making and using it, commensurate in scope to the claims. As such, the requirements of §112, first paragraph are satisfied and this rejection should be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all grounds for rejection have been addressed and should be removed, and that Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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[1] *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002)